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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,471	07/27/2001	Leland F. Wilson	9050-0053	3484

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EXAMINER

HUI, SAN MING R

ART UNIT PAPER NUMBER

1617

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,471

Applicant(s)

WILSON ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39,43-50 and 55 is/are pending in the application.
- 4a) Of the above claim(s) 13-15,19 and 46-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12,16-18,20-39,43-45,50 and 55 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Applicant's amendments filed November 13, 2002 have been entered. The cancellation of claims 40-42 and 51-54 in amendments filed November 13, 2002 is acknowledged. The addition of claim 55 in amendments filed November 13, 2002 is also acknowledged.

This application contains claims 46-49 drawn to an invention nonelected without traverse in Paper No. 3. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The outstanding rejections of claim 20 under 35 USC 112, first and second paragraph are withdrawn in view of the rebuttal argument filed November 13, 2002. The instant specification, page 10, discloses suitable lipoidal carriers for use in the instant invention.

The outstanding rejections of claims 1 and 50 under 35 USC 112, second paragraph are withdrawn in view of the rebuttal argument and amendments filed November 13, 2002.

Claims 1-39, 43-50 and 55 are pending.

Claims 46-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 13-15 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 3.

The claims have been examined herein to the extent they read on the elected invention and species.

Please note that the use of parenthesis in claim 1, line 7: "(SARMs)", is considered improper. Appropriate correction is required. Please note also the metes and bounds of claim 1 is not clear because it recites the limitation "other peptidyl drugs". Although applicant attempts to define what peptidyl drugs are suitable for the instant invention, it is unclear what other peptides are encompassed by the claim because the claim reads on all peptides known to man.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 16-18, 20-39, 43-45, 50, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (WO 99/66909) and Place et al. (US Patent 5,877,216), references of record.

Adams teaches a method of treating female sexual dysfunction employing a dopaminergic agonist, apomorphine and concomitantly with an androgenic agent such as dihydrotestosterone and its ester (See claims 1-3, 11-12). Adams also teaches that the androgenic agent may be administered orally (See page 21, line 13-25). Adams

also teaches that dihydrotestosterone may be administered prior to or concomitantly with apomorphine (See claims 16-17). Adam also teaches that 480 μ g/kg dose of one of the androgenic agent, testosterone, 36 hours prior to the administration of apomorphine are effective to alleviate sexual dysfunction or normalize sexual dysfunction in post-menopausal and pre-menopausal women (See page 32, line 10-23).

Adams does not expressly teach the androgenic agent is dihydrotestosterone propionate. Adams does not expressly teach the addition agent to be a prostaglandins or prostaglandin derivative such as carboprost tromethamine. Adams does not expressly teach the addition agent to be administered topically. Adams does not expressly teach the dosing regimen and dosage of the androgenic agent and the secondary active herein. Adams does not expressly teach the employment of a lipoidal carrier to enhance the bioavailability of the androgenic agent. Adams also teaches that the active agents can be formulated into unit dosage form (See page 22, line 5-11).

Place et al. teaches PGE₀ or carboprost tromethamine topical administration is effective in a method of treating female sexual dysfunction (See claims 5 and 9). Place et al. also teaches steroids such as dihydrotestosterone may be employed with the prostaglandins in the method of treating female sexual dysfunction (See claim 10; also col. 8, line 32-47). Place et al. also teaches an additional agent such as detergent may be incorporated into the female sexual dysfunction treating method in increase the solubility and bioavailability of active agents (See particularly claim 13). Place et al. also teaches that the pharmaceutical composition therein can be formulated into liposomal formulation (See particularly claim 20). Place et al. also teaches that the dosage of

prostaglandin for the treatment of female sexual dysfunction would be at least the dosage of dyspareunia treatment which is 50 to 500 μ g/kg (around 3 to 30mg for an average 60kg female) (see col. 13, line 41-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ dihydrotestosterone propionate with a second active agent such as PGE₀, carboprost tromethamine, or apomorphine, in the dosage range and regimen herein, in the method of treating female sexual dysfunction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a lipoidal carrier to enhance the bioavailability of the androgenic agent.

One of ordinary skill in the art would have been motivated to employ dihydrotestosterone propionate with a second active agent such as PGE₀, carboprost tromethamine, or apomorphine, in the dosage range and regimen herein, in the method of treating female sexual dysfunction because all of the dihydrotestosterone esters are known to be useful in treating female sexual dysfunction. Employing dihydrotestosterone propionate would have been reasonably expected to be similarly useful for treating female sexual dysfunction. Employing a second active agent such as PGE₀, carboprost tromethamine, or apomorphine into the method of treating female sexual dysfunction would have been reasonably expected to be effective based on the teachings of Adams and Place et al. Combining two or more agents which are known to be useful to treat female sexual dysfunction individually into a single composition and method useful for the very same purpose is prima facie obvious. See *In re Kerkhoven*

205 USPQ 1069. Furthermore, the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

One of ordinary skill in the art would have been motivated to employ a lipoidal carrier to enhance the bioavailability of the androgenic agent because based on Place et al. additive such as detergent can enhance the bioavailability of the active compounds. Therefore, employing a detergent into the liposomal formulation useful for treating female sexual dysfunction would have been reasonably expected to be useful for enhancing the bioavailability of the actives herein.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, the activities demonstrated in page 38 and 39 in the instant specification are expected based on the prior art. No convincing and clear unexpected result is seen.

Even though claim 55 recite the transitional phrase "consisting essentially of", the cited prior art, as a whole, still renders the claimed invention obvious as the additional component taught by the cited prior art does not change the basic and novel

characteristics of the invention, i.e., enhancing sexual desire and responsiveness in female individual.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic of the claimed invention. For the purpose of searching for and applying prior art under 35 USC 102 and 103, absent clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising" See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. ("PPG could have defined the scope of the phrase consisting essentially of for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that

a step practiced in a prior art method is excluded from his claims by `consisting essentially of language.") (See MPEP 2111.03).

Response to Arguments

Applicant's rebuttal arguments filed November 13, 2002 averring the instant invention not requiring apomorphine and the cited prior art failing to show testosterone compound alone being effective, have been fully considered but they are not persuasive. Please note that the claims herein drawn to method of enhancing female sexual desire comprising the administration of androgenic agent such as testosterone as the first active. The cited prior art teaches a method of enhancing female sexual desire comprising the administration of an androgenic agent. Since the claims are having an open transitional phrase, anything can be added to the method. Therefore, the cited prior art still renders the instant invention obvious.

Applicant's rebuttal arguments filed November 13, 2002 averring the second active agent to be orally administered, have been fully considered but they are not persuasive. There is no limitation directed to the route of administration of the second therapeutic agent. Please note that arguments drawn to unclaimed limitations are considered moot.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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San-ming Hui
January 29, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

2/9/03